

Appln. No. 09/942,463
Amdt. dated April 23, 2004

REMARKS

Claims 23-28 were pending in the above application per applicant's August 29, 2001 preliminary amendment. As amended, claims 23-35 are currently pending.

The Amendments

In a preliminary amendment dated August 29, 2001, applicant cancelled claims 1-22 without prejudice. Applicant hereby adds claims 29-35, to be examined together with claims 23-28.

Applicant has amended claim 24 to make it independent. Support for this amendment can be found in original claim 15.

The Restriction Requirement

In a communication dated March 24, 2003, the Examiner stated that restriction of the application into one of the following four inventions is required under 35 U.S.C. § 121:

- I. Claims 1-15, drawn to a complex comprising a target binding/cavity forming moiety, a cavity forming moiety, and a pharmacological compound.
- II. Claim 16-22, drawn to a method of delivering a pharmacological compound to a target in a patient.
- III. Claims 23, drawn to a method of purifying pharmacological compounds away from unwanted chiral forms.
- IV. Claims 24-26 [sic], drawn to a method for producing a complex.

Applicant traverses.

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The Examiner's Office Action Summary of March 24, 2003 states that claims 1-28 are pending in the application, however claims 27 and 28 have not been assigned to a restriction group. Applicant assumes that claims 27 and 28, which depend from claim 24, would fall within Group IV, as the Examiner has restricted the claims.

Originally filed claims 1-15 have issued in United States patent 6,406,710 (the "710 patent"). Claims 16-22 were cancelled per applicant's preliminary amendment dated August 29, 2001. The instant Amendment adds claims 29-35, such that claims 23-35 are now under consideration in the instant application. Claims 29-35 are directed to the same subject matter as originally filed claims 16-22.

The Instant Restriction

The Manual of Patent Examining Procedure (MPEP) states that there are two criteria for a proper requirement of restriction between patentably distinct inventions. The first is that the inventions must be independent or distinct as claimed. The second is that there must be a serious burden on the Examiner if restriction is not required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" MPEP § 803 (emphasis added).

The claims of Groups II-IV of the instant application are directed to methods of delivering a pharmacological compound, purifying a pharmacological compound or producing a complex for delivering a pharmacological compound. The claims of Groups II, III and IV of the instant application should not be separated from each other because the claims of each Group include as a common point of novelty -- the

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complex of now-issued claim 15. Searches for methods employing the complex of now-issued claim 15 in delivering or purifying a compound would necessarily be co-extensive with each other, as well as coextensive with a search for the methods for producing a complex for delivering a pharmacological compound, and would therefore not impose a serious burden on the Examiner.

The Examiner states that "Group II requires the search and consideration of efficacy of therapy by administration of a target binding moiety/cavity forming moiety/pharmacological compound complex to a patient, which is not required by the other inventions. Applicant respectfully disagrees. Efficacy of therapy is not required by the claims of Group II, only administration. As in the claims of Groups III and IV, there is the use of the complex of now-issued claim 15. Additional claim steps would not constitute an undue search burden where the complex employed in the method is known to be novel.

The Examiner's discussion at 1.b. and 1.c. regarding differences between Group I and Groups II/IV and III is moot, as the claims of Group I have issued.

Conclusion

1) Species Restriction

Applicant elects the following species for further prosecution in this application:

A method of delivering a pharmacological compound to a target in a patient, wherein the target is a cell.

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A method of delivering a pharmacological compound to a target in a patient, wherein the target is a protein and the protein is a cell surface protein.

A method of delivering a pharmacological compound to a target in a patient, wherein the target is a protein and the protein is trkA.

2) Claim Restriction

Applicant believes that Groups II, III and IV should be considered together because there is no undue search burden for the Examiner to examine the subject matter of these groups in a single application. If the Examiner does not agree with this proposal, pursuant to 37 C.F.R. § 1.143, applicant elects, with traverse, the claims of Group II, containing new claims 29-35 directed to methods of delivering a pharmacological compound to a target in a patient, for initial substantive examination. This provisional election is made expressly without waiver of applicant's rights to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or in other applications claiming benefit herefrom.

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Based on the above remarks, applicant requests that the Examiner withdraw the restriction of claims 23, 24-28 and 29-35 into three groups, and allow claims 23-35, as amended, to issue.

Respectfully submitted,



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